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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,219	01/12/2004	Donald R. Sandell	4696C1	1150

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MILA KASAN, PATENT DEPT.  
APPLIED BIOSYSTEMS  
850 LINCOLN CENTRE DRIVE  
FOSTER CITY, CA 94404

EXAMINER
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BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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01/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/756,219

**Applicant(s)**

SANDELL, DONALD R.

**Examiner**

William H. Beisner

**Art Unit**

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 52, 54 and 55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 52, 54 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/27/2007 has been entered.

### ***Claim Objections***

2. Claim 52 is objected to because of the following informalities: The status identifier associated with claim 52 is incorrect because claim 52 includes amended text. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 52 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rochte et al.(US 3,545,690) in view of Wheatcroft (CA 2,255,850).

The reference of Rochte et al. discloses a method for performing an automated chemical analysis on samples positioned in a sample well tray (24) in an incubation device (400). The method includes providing a translatable sample block assembly (402); moving the sample block assembly (402) from a first position permitting placement of the sample well tray onto the incubation device (400) to a second position permitting incubation within the incubating device (400) (See column 9, line 65, to column 10, line 21; and column 13, line 59, to column 14, line 3); positioning the sample well tray (24) onto the sample block assembly (402) to engage the sample well tray to the sample block assembly (See column 9, line 65, to column 10, line 21; and column 13, line 59, to column 14, line 3); maintaining the upper portion of the incubation device substantially stationary (See Figures 3 and 5 and See column 9, line 65, to column 10, line 21; and column 13, line 59, to column 14, line 3); and incubating the samples in the tray to perform the desired chemical reaction. Note the sample well tray (24) is configured so that it can horizontally translate into and out of the thermal cycling device. Specifically, the sample well tray (24) horizontally translates into and out of the thermal cycling device (400) along rails (22) and racks (26) (See column 3, lines 38-50; column 4, lines 34-64; and Figure 5).

Claim 52 differs by reciting that the sample includes nucleic acid and the chemical reaction performed is nucleic acid amplification by thermally cycling the sample mixture.

The reference of Wheatcroft discloses that it is known in the art to perform nucleic acid amplifications in an automated chemical analysis device the includes incubation stations (See page 2, lines 10-30; Figure 1; and page 7, line 36, to page 9, line 21).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to perform nucleic acid amplifications in the system of the primary reference of Rochte et al. for the known and expected result of providing an art recognized means for automating an analytical chemical reaction process. When modifying the reference of Rochte et al. as discussed above, the sample block assembly (402) control would be cycled to provide the thermal cycling required to perform nucleic acid amplifications.

With respect to claim 55, both the references of Rochte et al. and Wheatcroft disclose that operation of the devices is automated (See the abstract of Rochte et al. and column 7, lines 31-36, of Wheatcroft).

6. Claims 52, 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rochte et al.(US 3,545,690) in view of Wheatcroft (CA 2,255,850) taken further in view of Woudenberg et al.(US 5,928,907).

The combination of the references of Rochte et al. and Wheatcroft has been discussed above.

Claims 52, 54 and 55 differ by requiring that the second position allows alignment of the sample well tray with an substantially stationary optical detection system and detecting the amplification during the thermal cycling.

The reference of Woudenberg et al. discloses that it is known in the art to configure a cover or platen (14) that is heated within an integrated optical detection system (10, 8, 6, 4, 2) (See Figure 1) such that the contents of the sample wells can be detected during the thermal cycling process.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the incubation station of the modified primary with an optical detection system as suggested by the reference of Woudenberg et al. for the known and expected result of providing a means recognized in the art for providing real-time fluorescence detection of the thermal cycling reaction within the sample wells.

### ***Response to Arguments***

7. With respect to the rejection of Claim 52 under 35 U.S.C. 103(a) as being unpatentable over Rochte et al.(US 3,545,690) in view of Wheatcroft (CA 2,255,850) and Claims 52 and 54 under 35 U.S.C. 103(a) as being unpatentable over Rochte et al.(US 3,545,690) in view of Wheatcroft (CA 2,255,850) taken further in view of Woudenberg et al.(US 5,928,907), Applicant argues that the rejections of the claims are improper for the following reasons.

i) *The cited references fail to provide the necessary motivation, which motivation cannot be found either in the references alone, or in combination* (See page 5 of the response dated 10/27/2007).

In response, as indicated by the Supreme Court, KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See *KSR International Co. v. Teleflex Inc.*, 550 U.S.----, 82 USPQ2d 1385, 1397 (2007).

Furthermore, the *KSR* decision makes clear that the teaching, suggestion, or motivation (TSM) test is not the only rationale that may be relied upon to support a conclusion of obviousness. In this case, the Examiner has articulated the following: i) a finding that the prior art contained a "base" method (Rochte et al.) upon which the claimed invention can be seen as an "improvement"; ii) a finding that the prior art (Wheatcroft) contained a known technique (performing nucleic acid amplification within an automated chemical analyzer) that is applicable to the base method (Rochte et al.); and iii) a finding that one of ordinary skill in the art would have recognized that applying the known technique would have yielded predictable results (automation of a nucleic amplification process) and resulted in an improved system (use of the system of Rochte et al. to perform nucleic amplification). As a result, the Examiner is of the position that a *prima facie* case of obviousness has been established as required under 35 USC 103(a).

ii) *The combined teachings of the references of Rochte et al. and Wheatcroft do not disclose the advantages associated with horizontal translation of the sample tray as is now recited in amended claim 52* (See page 4 of Applicant's response dated 10/27/2007).

In response to applicant's argument above, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In this case, the method resulting from the combination of the references as discussed in the prior art rejection above would result in a thermal cycling method wherein the sample tray horizontally translates into and out of the thermal cycler section of the device.

*Conclusion*

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/  
Primary Examiner  
Art Unit 1797

WHB